EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K061160

JUN - 9 2006

1. Submitter's Identification:

VuComp, Inc.
6509 Windcrest Drive, Suite 160
Plano, Texas 75024

Contact: Mr. Stuart Barab
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email: stuart.barab@vucomp.com

Date Summary Prepared: April 20, 2006

2. Name of the Device:

M-Vu™ CAD Station

3. Predicate Device Information:

Consultiva™ Case Input Station, K#031132, MiraMedica, Inc. Los Gatos, CA.

4. Device Description:

The M-Vu™ CAD Station is a computer-based system that supports the acquisition and storage of medical images for subsequent digital analysis and processing. The system can obtain digitized imagery from two sources: 1) digitized film images from a medical digitizer that is included as part of the system or 2) digitized images obtained from different sources and sent to the CAD Station via a DICOM network interface. The CAD Station is not intended as an archival device.

The CAD Station has several commercial components integrated together on a custom cart. The components include a 510(k)-cleared medical digitizer for scanning films, a printer for report generation, a touch screen monitor for control and displaying system status and error messages, a Windows™-OS computer

for executing control software and for temporary storage of imagery and an uninterruptible power supply. The CAD Station communicates via a standard Ethernet network and can support an interface to other PACS devices through a DICOM interface. It also communicates to the M-Vu™ Viewer Station (K060451) to provide case reports including low resolution radiographic images.

The user interface to the CAD Station is via a touch screen monitor. The monitor allows control of the digitizer and provides system status information. While the system is intended to be operated in an unattended batch mode, case priorities can be manually adjusted for higher priority film or digital cases. Also, user specific configuration information and options can be accessed through an on-screen keyboard.

The printer automatically generates case reports with low resolution imagery and a printed (unique) bar code. The bar code is then used to link the case reports to the graphical imagery on the M-Vu Viewer Station.

5. Intended Use:

The M-Vu™ CAD Station is intended to support the acquisition and storage of medical images for subsequent digital analysis and processing. The medical imagery can be obtained from film format (digitized by a commercial FDA-cleared medical digitizer) or digital format transmitted via a standard DICOM network interface. The CAD Station can print case information and can connect over a Local Area Network and interface with the M-Vu Viewer Station. The CAD Station is intended for use by a technician under the supervision of a medical professional.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.

6. Comparison to Predicate Devices:

Similarities and Differences are as follows:

- Both devices are intended to facilitate the acquisition of digital imagery in a medical environment. They have similar functionality and utility.
- Both devices utilize a medical digitizer to obtain film imagery but the M-Vu device can also obtain digital imagery via a DICOM interface.
- The predicate device has an automatic film recognition and ordering feature that is not offered by the M-Vu device. The M-Vu device depends on films being ordered as described in the User Manual.

In summary, both the subject and predicate devices are the same or very similar in significant aspects including the intended use of the devices.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the M-Vu™ CAD Station device in the intended environment of use is supported by testing that was conducted for safety and performance, including software validation and verification testing. Results of the testing revealed that the M-Vu CAD station is substantially equivalent to the predicate device.

8. **Discussion of Clinical Tests Performed:**

Not applicable

9. **Conclusions:**

The M-Vu™ CAD Station device has a very similar intended use and similar characteristics as the predicate device. Moreover, software testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the M-Vu CAD Station device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN - 9 2006

VuComp, Inc.
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd.m Suite 200
GREAT NECK NY 11021

Re: K061160
Trade/Device Name: M-Vu™ CAD Station
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 24, 2006
Received: April 26, 2006

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit B

510(k) Number (if known): K061160

Device Name: M-Vu™ CAD Station

Indications For Use:

The M-Vu™ CAD Station is intended to support the acquisition and storage of medical images for subsequent digital analysis and processing. The medical imagery can be obtained from film format (digitized by a commercial FDA-cleared medical digitizer) or digital format transmitted via a standard DICOM network interface. The CAD Station can print case information and can connect over a Local Area Network and interface with the M-Vu Viewer Station. The CAD Station is intended for use by a technician under the supervision of a medical professional.

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Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David K. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061160